REMARKS

The Final Office Action mailed June 14, 2010, has been received and reviewed. Claims 1-6, 8, 9, 11-14, 16-18, 20-23, 25-31, 33-40, and 42-51 are pending in the subject application. All pending claims stand rejected under 35 U.S.C. § 103(a).

In order to expedite allowance of the rejected claims, without conceding to the validity of the Office's rejections, claims 1, 5, 6, 11-13, and 18 are amended, while claims 2, 4, 8, 9 are canceled and claims 52-63 are added, as set forth herein. As such, upon entry of these changes, claims 1, 3, 5, 6, 11-14, 16-18, 20-23, 25-31, 34, and 52-63 will remain pending. It is submitted that no new matter has been added by way of the present proposed amendments. Reconsideration of the subject application is respectfully requested in view of the proposed amendments and the following remarks.

Support for Claim Amendments

Independent claim 1 has been amended herein to recite a clarification of the process of acquiring a "genetic test result value for the associated gene of a person" when it is not available at the person's EMR. In particular, the acquiring process comprises the following steps:

a) "determining whether to seek a clinician's authorization to order a test of the person or whether to order the test without the clinician's input based on both a likelihood of one or more genetic variations of the associated gene occurring and a severity of interaction of the one or more occurring genetic variations with the clinical agent;"

b) "when the severity and the likelihood of the associated gene's one or more genetic variations indicate ordering the test without the clinician's input, automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available;"

c) "when the severity and the likelihood of the associated gene's one or more genetic variations indicate seeking the clinician's authorization to order the test, seeking a clinician's authorization for the test by presenting a genetic test ordering window;" and

d) "automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available and the authorization is granted by a clinician at the genetic test ordering window."

Support for this claim amendment may be found in the Specification, for example, at paragraphs [0037] – [0039].

Independent claim 18 has been amended herein to recite a clarification of the process of utilizing a displaying component to present feedback to a clinician/doctor/medical staff pertaining, wherein presenting comprises the following steps:

a) "receiving the determination from the third determining component of whether the risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent;"

b) "displaying in a notification window a value of a lower dosage of the clinical agent to be prescribed when the risk of damage is less than not administering the clinical agent;" and

c) "displaying in the notification window a warning to the clinician that the clinical agent should not be administered to the person when the risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent."

Support for this claim amendment may be found in the Specification, for example, at paragraphs [0043] and [0052] – [0055].

In general, proposed amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132, unless they disclose an invention, process, or

apparatus not theretofore described. Further, if later-submitted material simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3] Accordingly, because these proposed amendments are explicitly discussed, and/or inherent to, the procedure for providing information about the risk of an atypical event based upon genetic information, as memorialized in the Detailed Description, the newly recited subject matter is encompassed by the scope of the Specification and does not constitute new matter.

Rejections based on 35 U.S.C. § 103

A.) Unpatentable Rejection Over U.S. Publication No. 2002/0110823 to Hogan in View of U.S. Patent No. 5,950,630 to Portwood et al., U.S. Patent No. 5,985,670 to Markin, and U.S. Publication No. 2002/0052761 to Fey et al.

Claims 1-6, 11-14, 16, 18, 20-23, 27-31, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hogan[4] in view of Portwood et al.[5] (hereinafter Portwood), Markin,[6] and Fey et al.[7] (hereinafter Fey). As the Hogan, Portwood, Markin, and Fey references, whether taken alone or in combination, do not describe, either expressly or inherently, each and every element of amended independent claims 1 and 18, or the claims that depend therefrom, the

[1] *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).
[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).
[3] *See id.*
[4] U.S. Publication No. 2002/0110823.
[5] U.S. Patent No. 5,950,630.
[6] U.S. Patent No. 5,985,670.

Applicants respectfully consider the pending rejection of these claims overcome, as hereinafter set forth. Further, claims 2 and 4 have been canceled by way of the present communication and, accordingly, the rejections of these claims have been rendered moot.

Independent claim 1 has been amended herein to recite a clarification of the process of acquiring a "genetic test result value for the associated gene of a person" when it is not available at the person's EMR, while independent claim 58 (formerly independent claim 55 of parent Application No. 10/826,595 (CRNI.114070)) is added to recite substantially similar subject matter. In particular, with respect to claim 1, the acquiring process comprises the following steps:

a) "determining whether to seek a clinician's authorization to order a test of the person or whether to order the test without the clinician's input based on both a likelihood of one or more genetic variations of the associated gene occurring and a severity of interaction of the one or more occurring genetic variations with the clinical agent;"
b) "when the severity and the likelihood of the associated gene's one or more genetic variations indicate ordering the test without the clinician's input, automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available;"
c) "when the severity and the likelihood of the associated gene's one or more genetic variations indicate seeking the clinician's authorization to order the test, seeking a clinician's authorization for the test by presenting a genetic test ordering window;" and
d) "automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available and the authorization is granted by a clinician at the genetic test ordering window."

[7] U.S. Publication No. 2002/0052761.

In this way, the administration of a test on a patient to ascertain a genetic test result value is initially conditioned on the two criteria of (a) the likelihood of genetic variation(s) of the associated gene occurring, and (b) the severity of interaction of the occurring genetic variation(s) with the clinical agent. Based on the above determination (using criteria (a) and (b)), the process either automatically orders the test without the clinician's input (presumptively when the likelihood and severity are high), or seeks authorization of the clinician to order the test (presumptively when the likelihood and severity are low).

With respect to new independent claim 58 the acquiring process (i.e., "obtaining a genetic test result value for the associated gene of the patient") comprises the following steps:

a) "determining whether to request authorization from a clinician to carry out the genetic test based on three criteria, a cost of the genetic test, whether the genetic test is available, and a likelihood of a genetic variation based on demographic information of the patient;"

b) "when the three criteria indicate authorization is needed, seeking the clinician's authorization for the genetic test by displaying a genetic test ordering window at the GUI;" and

c) "when the three criteria indicate no authorization is needed, automatically ordering the genetic test to determine the genetic test result value for the associated gene of the patient."

In this way, the administration of a test on a patient to ascertain a genetic test result value is initially conditioned on the three criteria of (a) a cost of the genetic test, (b) whether the genetic test is available, and (c) a likelihood of a genetic variation based on demographic information of the patient. Based on the above determination (using criteria (a) - (c)), the process either automatically orders the test without the clinician's input, or seeks authorization of the clinician to order the test.

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[8] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[9] When determining whether a claim limitation is taught, "All words in a claim must be considered in judging the patentability of that claim against the prior art."[10] Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."[11]

Significantly, it should be noted that the two criteria of claim 1 and the three criteria of claim 58 are respectively considered in conjunction to arrive at a decision, as discussed during the Examiner Interview. As such, simply combining references that might consider some of the criteria individually does not enable a hypothetical process that would render claims 1 and 58 obvious.

The Office indicates that the combination of Hogan and Portwood do not explicitly teach seeking a clinician's authorization for a test by presenting a genetic test ordering window. The Office contends that Markin teaches a computerized system that enables a doctor to enter a request for a specific test, while Fey teaches a graphical user interface for ordering tests. However, the proposed combination of Markin and Fey, along with Hogan and Portwood, does not explicitly disclose or implicitly consider the two combinations of criteria above.

[8] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[9] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[10] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).

Instead, the cited portions of Markin teach only the fact that a doctor may "make a record for examination results, and may enter a request for a specific test to be performed."[12] Meanwhile, the cited portions of Fey teach client-ordered tests that do not require a physician's referral for the sake of "ensuring absolute anonymity,"[13] which teaches away from involving the clinician in the test-ordering process.

Further, the Office relies heavily on the primary reference, Hogan, for its discussion of cost-effectiveness and the importance of cost when performing preoperative testing of patients.[14] However, Applicants respectively assert that it is overreaching to suggest that all process steps (performed when determining whether to order a genetic test) in claims 1 and 58 that may result in a cost-savings are implicitly considered by Hogan. Moreover, Hogan in combination with the other cited references above do not explicitly describe or implicitly consider using criteria to make the very specific determination of whether to "seek a clinician's authorization to order a [genetic] test of the person or whether to order the test without the clinician's input."

Further, the proposed combination of references does not teach the particular criteria (inputs) for this making this specific determination, such as claim 1's "a likelihood of one or more genetic variations of the associated gene occurring and a severity of interaction of the one or more occurring genetic variations with the clinical agent." Last, as stated above, it should be noted that various criteria (e.g., cost of the test)[15] for making the automatic vs. manual test-ordering determination are considered in light of the other criteria, as opposed to being considered in isolation.

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[11] *Ex parte Clapp*, 227 USPQ 972, 972 (Bd. Pat. App. & Inter. 1985); *see also* MPEP §706.02(j) and §2142.
[12] *Markin* at col. 3, ll. 3-19.
[13] *Fey* at ¶ [0057].
[14] *Hogan* ¶¶ [0030] – [0034].

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claims 1 and 58 be withdrawn. Further, claims 1 and 58 are believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 2-63, 5, 6, 11-14, 16, 52-57, and 59-63 depend, either directly or indirectly, from one of independent claims 1 and 58, respectively. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[16]

Independent claim 18 has been amended herein to recite a clarification of the process of utilizing a displaying component to present feedback to a clinician/doctor/medical staff pertaining, wherein presenting comprises the following steps:

a) "receiving the determination from the third determining component of whether the risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent;"

b) "displaying in a notification window a value of a lower dosage of the clinical agent to be prescribed when the risk of damage is less than not administering the clinical agent;" and

c) "displaying in the notification window a warning to the clinician that the clinical agent should not be administered to the person when the risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent."

In this way, the contents of the notification window correspond to the result of the determination of "*whether the risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent*" (emphasis added). Specifically, "when the risk of damage is less than not administering the clinical agent," the notification window presents "a value of a lower dosage of the clinical agent to be prescribed."

[15] Specification at ¶ [0038].

On the other hand, "when the risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent," the notification window presents "a warning to the clinician that the clinical agent should not be administered to the person."

Applicants recognize that Hogan discusses assessing the dosages associated with clinical agents at paragraphs [0005], [0008], and [0138]. In particular, Hogan discloses the following: "Complications can be avoided by substituting other medications or adjusting dosage."[17] However, Hogan does not consider the very specific risk-analysis determination recited above in claim 18, which is made by the third determining component. Accordingly, it is an over-generalization to suggest that Hogan's process of adjusting a dosage to avoid complications from adverse drug reactions renders obvious the specific risk-of-damage balancing between "not administering the clinical agent" and "lowering the dosage of the clinical agent." Further, none of the above-cited reference, alone or in combination, cure this deficiency of Hogan by implicitly or explicitly by teaching a determination of whether a risk of damage to a person is greater by weighing these two specific criteria.

Applicants additionally assert that, although Markin and Fey are cited for teaching a GUI designed for a doctor to order test, the combination of the above-cited references to not implicitly consider varying the contents displayed in a notification window based on the results of the risk-of-damage determination discussed immediately above. That is, the Office's proposed combination do not render obvious (i) "displaying in a notification window a value of a lower dosage of the clinical agent to be prescribed when the risk of damage is less than not administering the clinical agent," or (ii) "displaying in the notification window a warning to the

[16] *See* 37 C.F.R. § 1.75(c) (2006).
[17] *Hogan* at ¶ [0008].

clinician that the clinical agent should not be administered to the person when the risk of damage of not administering the clinical agent is less than lowering the dosage of the clinical agent."

In view of the above, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of claim 18 be withdrawn. Further, claim 18 is believed to be in condition for allowance and such favorable action is respectfully requested. Each of claims 20-23, 27-31, and 33 depend, either directly or indirectly, from independent claim 18. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[18]

C.) Obviousness rejection based upon Hogan in view of Portwood in view of Markin and further in view of Fey and further in view of U.S. Patent No. 6,219,674 to Classen

Claims 35-40 and 44-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hogan in view of Portwood, Markin, Fey, and U.S. Patent No. 6,219,674 to Classen. Claims 35-40 and 44-50 have been canceled by way of the present communication and, accordingly, the rejections of these claims have been rendered moot. (The subject matter of these claims has been canceled from the instant child application and added to the parent Application No. 10/826,595 (CRNI.83071) as independent claim 94 and its dependents.)

[18] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, upon entry of the proposed amendments, it is believed that claims 1, 3, 5, 6, 11-14, 16-18, 20-23, 25-31, 34, and 52-63 will be in condition for allowance. As such, Applicants respectfully request entry of the proposed amendments, withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or btabor@shb.com (such communication via email is herein expressly granted) – to resolve the same. A Request for Continued Examination Fee is submitted herewith. It is believed that no additional fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.114070.

Respectfully submitted,

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